510(k) Summary

Submitter:	Edwards Lifesciences Research Medical, Inc.
Contact Person:	Karen Jones, Senior Manager, Regulatory Affairs 6864 South 300 West Midvale, UT 84047 801-565-6231
Date Prepared:	xxxxxx
Trade Name:	Edwards Lifesciences Venous Cannula
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass 21 CFR Part 870.4210, Product Code DWF, Class II
Predicate Device:	Edwards Lifesciences Venous Cannula

OCT - 8 2009

Device Description:
Edwards venous cannulae are polymeric tubes intended to provide a means of returning de-oxygenated blood from a patient to the oxygenator during cardiopulmonary bypass procedures.

The cannulae are available in a range of sizes and types and in a variety of tip and hole configurations. Variants include codes with ½" to ¼" acceptance or connectors. Cannulae are reinforced by means of a stainless steel wire entirely encapsulated within the wall of the cannula to minimize the potential for cannula kinking. The devices are provided sterile, they are non-pyrogenic and they are intended for single use only.

Intended Use:
The dual drainage venous return cannulae are indicated for venous cannulation so that extracorporeal circulation of the venous blood to a heart-lung machine may be achieved, for a duration of < 6 hours.

They are also indicated for coronary bypass procedures where single tube venous drainage from the right atrium only is ordinarily contraindicated because of diminished caval return due to intra-operative manipulation of the heart.

Venous return cannulae in sizes 6Fr to 18Fr can be used in pediatric patients.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin-coated blood path is desired.

Comparative Analysis:
It has been demonstrated that the proposed venous cannulae are comparable to the predicate devices in intended use and other labeling, fundamental scientific technology, material type, principles of operation and functional performance evaluations.

Functional/Safety Testing: The functional data indicate that the proposed devices perform in a substantially equivalent manner when compared with the predicate device.

Conclusion:
The venous cannulae are substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Edwards Lifesciences, LLC
c/o Ms. Karen Jones
Senior Manager, Regulatory Affairs
6864 South 300 West
Midvale, Utah 84047

OCT - 8 2009

Re: K092509
Edwards Lifesciences Venous Return Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: August 14, 2009
Received: August 17, 2009

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092509

Device Name: Edwards Lifesciences Venous Return Cannulae

Indications for Use:

- Dual drainage venous return cannulae are indicated for venous cannulation so that extracorporeal circulation of the venous blood to a heart-lung machine may be achieved, for a duration of < 6 hours.
- They are also indicated for coronary bypass procedures where single tube venous drainage from the right atrium only is ordinarily contraindicated because of diminished caval return due to intra-operative manipulation of the heart.
- Venous return cannulae in sizes 6Fr to 18Fr can be used in pediatric patients.
- Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin-coated blood path is desired.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Mund

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092509